UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.,* *ex rel.* JULIANNE NUNNELLY and MATTHEW SHANKS Plaintiffs, v. REGENERON PHARMACEUTICALS, INC., Defendant.	)	No. 20-cv-11401-PBS

UNITED STATES' COMPLAINT IN INTERVENTION
AGAINST REGENERON PHARMACEUTICALS, INC.

By notice to the Court on November 27, 2023, the United States of America partially intervened in the above-captioned case. The United States alleges as follows with respect to Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron"):

Introduction

1. The United States, on behalf of the United States Department of Health and Human Services ("HHS") and its component agency, the Centers for Medicare and Medicaid Services ("CMS"), brings this action against Regeneron, which manufactures Eylea, a drug that is indicated to treat certain forms of macular degeneration and other ophthalmological conditions. The United States brings this action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, seeking treble damages and penalties, and under the common law.

2. Since bringing Eylea to market in late 2011, Regeneron has paid hundreds of millions of dollars to subsidize Eylea purchases by reimbursing distributors for credit card processing fees—on the condition that the distributors use these payments to lower the effective

price they charged for Eylea to doctors and retina practices using credit cards. From 2012 to 2021, Regeneron's credit card fee reimbursements for Eylea purchases exceeded $250 million to just one of its several distributors. Regeneron paid those fees so that doctors and retina practices that purchased Eylea could use credit cards at no additional cost and obtain hundreds of millions of dollars in "cash back" rewards and other credit card benefits on their Eylea purchases. Regeneron's subsidy payments were price concessions that Regeneron should have included in its price reporting to CMS for Eylea. Regeneron knowingly excluded the credit card processing fee payments in its price reports, however, thereby falsely inflating Medicare reimbursements for Eylea and giving Regeneron an unfair competitive advantage. Regeneron's conduct, and the resulting harm to Medicare, is ongoing.

3. Eylea is a physician-administered injectable drug that treats a form of macular degeneration called Neovascular Age-Related Macular Degeneration, commonly known as Wet AMD. Wet AMD is a prevalent, progressive retina degenerative macular disease that leads to gradual vision impairment, and which mainly affects the elderly. Physicians typically administer Eylea by injecting the drug into patients' eyes at the physician's practice on an outpatient basis. The administration of Eylea is a top Medicare expense. Medicare Part B paid more than $25 billion for Eylea between 2012 and 2023.

4. Eylea is a "buy-and-bill" drug, meaning that physicians and their practices incur an upfront expense to purchase Eylea that payors later reimburse. Retina surgeons, injecting ophthalmologists, and their practices (referred to herein as Eylea "customers" or "retina practices") typically purchase Eylea from third-party distributors.[1] To distribute Eylea,

[1] Regeneron sold, and continues to sell, a small portion of Eylea through specialty pharmacies, but it made the vast majority of its Eylea sales through distributors to retina practices on a "buy-and-bill" basis, and continues to do so.

Regeneron initially entered into distribution contracts with Besse Medical ("Besse"), McKesson Corporation ("McKesson"), and CuraScript SD Specialty Distribution ("CuraScript"), and later also contracted with Metro Medical, a division of Cardinal Health.[2] Once a physician administers Eylea to a patient, the retina practice submits a claim for reimbursement to Medicare or other payors.

5. Medicare Part B reimburses Eylea and other physician-administered drugs based on the average sales price ("ASP") of the drug—typically 106% of ASP, referred to as "ASP+6%"—less the applicable patient co-pay. *See* 42 U.S.C. § 1395w–3a(b). A drug's ASP is based on the average price for sales of that drug in the United States, minus price concessions. 42 C.F.R. § 414.804(a)(1). CMS requires drug manufacturers to report the ASP of each of their Part B drugs on a quarterly basis, 42 C.F.R. § 414.804(a)(5), and relies on manufacturers to truthfully and accurately report ASP. The difference between the Medicare reimbursement rate and the amount the customer pays to purchase the drug is referred to as the "spread," which is the customer's (*i.e.*, the physician's or practice's) profit on the drug. Thus, an overstated ASP inappropriately increases the spread or profit that customers receive for each claim they submit to Medicare. For example, a manufacturer's failures to report all price concessions will increase the spread, or profit, customers receive on each claim Medicare reimburses.

6. Regeneron failed to report an applicable price concession. It knew that distributors incurred credit card processing fees when customers used credit cards, and that as a result, distributors typically charged retina practices a higher price to use credit cards for high-cost drugs like Eylea in order to offset the cost of those fees. For example, Besse, the largest

[2] Regeneron also contracted with Avella of Deer Valley, Inc., f/k/a Apothecary Shop, as both a specialty pharmacy and distributor, although it had a small volume as a distributor from 2011 to approximately 2015.

Eylea distributor, stated on the invoices it issued to customers and to Regeneron that "Prices on this invoice reflect a discount for payments received by cash . . . . Payments by credit cards will not receive this cash discount." Customers who used credit cards thus usually paid a higher price than customers paying in "cash" (*i.e.*, a wire or check payment). As explained below, Regeneron paid Besse and other distributors for the credit card processing fees so that they would extend the lower cash pricing to customers, knowing that it was a price concession to Eylea customers who valued the ability to use credit cards at that lower price.

7. Regeneron knew that paying the credit card processing fees enabled customers to purchase Eylea from distributors with a credit card at a lower amount than the distributors otherwise would have charged—and Regeneron knew retina practices did not always have the same opportunity to pay with credit cards for competing products, such as Avastin, which was the drug physicians most commonly administered to patients to treat Wet AMD until Eylea surpassed its market share in or around 2016.

8. Regeneron meticulously tracked how much it paid distributors in credit card processing fees for retina practices' Eylea purchases. Regeneron received monthly credit card fee invoices from distributors, along with spreadsheets that itemized the credit card fees for each Eylea purchase. Regeneron reviewed those invoices and spreadsheets and reconciled them against its own records as part of its process for approving and paying those invoices. And these fees were substantial: between 2012 and mid-2021, Regeneron paid over $250 million to Besse alone for Eylea customers' credit card fees.

9. By paying these fees, Regeneron ensured that retina practices could use credit cards to purchase Eylea without incurring a higher price *and* that they received the associated

benefits, particularly "cash back" (often one to two percent of the purchase amount) and other rewards on their Eylea purchases.

10. Regeneron knew retina practices closely tracked their revenue and margins on Eylea, and many received hundreds of thousands, and in some cases millions, of dollars in "cash back" from their Eylea purchases. For example, one retina practice calculated its profits on drugs over a 1-year period, with Eylea purchases of $39,485,240 and a "Credit card rebate %" of "1.89%"—which yielded $746,274 for Eylea alone. At some retina practices, credit card "cash back" and other rewards went directly into doctors' pockets, with doctors making Eylea purchases on their personal credit cards—and taking turns or using multiple credit cards per invoice so doctors could directly receive the credit card rewards.

11. In accordance with the government's price reporting requirements, Regeneron submitted quarterly ASP reports for Eylea to CMS. Regeneron knew the law required it to deduct price concessions from Eylea's ASP. *See* 42 C.F.R. § 414.804(a)(2)(i) ("In calculating the manufacturer's average sales price, a manufacturer *must* deduct price concessions.") (emphasis added). Regeneron nonetheless deliberately chose not to report those payments as price concessions as part of a strategy to maintain a steady and inflated ASP for Eylea, which in turn ensured steady—and inflated—Medicare reimbursement rates for Eylea.

12. Regeneron internally discussed whether these payments could qualify as "bona fide service fees" ("BFSFs"), which are not considered price concessions that must be deducted from ASP. Regeneron knew, however, that the credit card processing fee payments failed multiple requirements to qualify as BFSFs, and that failure of any one requirement disqualified the payments as BFSFs. *See* 42 C.F.R. § 414.802.

13. Regeneron knew its payments were price concessions that subsidized customers' Eylea purchases, and knew it was obligated to report them to CMS, and yet, Regeneron knowingly failed to deduct them as price concessions in its ASP reports.

14. Regeneron thus knowingly submitted false ASP reports and inflated the amount that Medicare Part B has paid for Eylea, and continues to pay, for each claim, causing the submission of hundreds of thousands of false claims to Medicare, and resulting in hundreds of millions of dollars in damages to the government.

15. By improperly inflating Eylea's ASP, Regeneron also created financial incentives for customers to purchase and use Eylea, which they did, and which Medicare reimbursed (at rates directly linked to Eylea's inflated ASP), thereby unjustly enriching Regeneron at the United States' expense.

Jurisdiction And Venue

16. This Court has subject matter jurisdiction under 28 U.S.C. § 1345, 1367(a). The Court may exercise personal jurisdiction over Regeneron, and venue is appropriate in this Court under 31 U.S.C. § 3732(a), because Regeneron caused false claims to be submitted in this District.

Parties

17. The United States brings this action on behalf of HHS, which administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* ("Medicare").

18. Relators are former Regeneron employees. Relator Julianne Nunnelly is a former Regional Sales Director at Regeneron. Relator Matthew Shanks is a former Director of Analytics.

19. Regeneron is a manufacturer and seller of pharmaceutical products, including Eylea. Regeneron has its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Regeneron conducts business nationwide, including in this District.

Background

I. The Medicare Program

20. Congress established Medicare in 1965 to provide health insurance coverage for people aged sixty-five or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395 *et seq*.

21. Medicare is funded by the federal government and administered by CMS, which is part of HHS. The Medicare program consists of four parts: A, B, C, and D. The Eylea claims at issue were billed and paid under Medicare Part B. Medicare Part B primarily covers outpatient medical services and physician-administered prescription drugs and biologicals, including injectable drugs used to treat macular degeneration, such as Eylea. 42 U.S.C. § 1395k(a).

22. Under Medicare Part B, providers submit claims for reimbursement to Medicare contractors, referred to as Medicare Administrative Contractors ("MACs"), which act as CMS agents in reviewing and paying claims submitted by health care providers. 42 U.S.C. §§ 1395u; 1395kk-1; 42 C.F.R. § 421.100.

23. Regeneron's customers submit claims for Wet AMD drugs, including Eylea, to Medicare Part B, via MACs, using a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent, known as the 837P form. Among the information the provider includes on CMS 1500 or 837P forms are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System

("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought. The CPT/HCPCS code for Eylea is currently J0178.

24. Once beneficiaries meet their annual deductible, Medicare Part B pays 80% of the cost of prescription drugs administered by a physician in an outpatient setting. 42 U.S.C. § 1395l(a)(1). Some Medicare beneficiaries purchase a supplemental insurance product, called a Medigap plan, to cover the remaining 20% co-pay. Others are responsible for covering that co-pay directly. *See* Medicare.gov, *Costs*, https://www.medicare.gov/basics/costs/medicare-costs.

II. ASP And Reimbursement Rates For Medicare Part B Drugs

25. Medicare Part B pays providers a statutorily determined reimbursement rate for physician-administered drugs that is set at 106% of the drug's reported ASP (*i.e.*, ASP+6%). 42 C.F.R. § 414.904.[3] CMS posts the Medicare payment rate, also called a "payment limit," for each HCPCS code, and sends them to Medicare contractors for claims processing, prior to the next quarter. *See, e.g.*, *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, HHS-OIG Report, pp. 3-4 (Feb. 2010), https://oig.hhs.gov/oei/reports/oei-03-08-00480.pdf; CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 12422, *April 2024 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files*, https://www.cms.gov/files/document/r12422cp.pdf. Thus, there is a two-quarter lag between the time when sales reflected in the ASP occur and the time when these sales become the basis for Medicare payment amounts.

26. ASP is statutorily defined as the "manufacturer's sales to all purchasers . . . in the United States for such drug or biological in the calendar quarter; divided by [] the total number

[3] While some physician-administered drugs covered by Medicare Part B share a CPT/HCPCS code, Eylea is the only drug that uses J0178.

of such units of such drug or biological sold by the manufacturer in such quarter." 42 U.S.C. § 1395w–3a(c)(1)(A)-(B).

27. The ASP "shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates . . . ." *Id.* § 1395w–3a(c)(3). The statute continues: "For years after 2004, the Secretary may include in such price other price concessions . . . that would result in a reduction of the cost to the purchaser." *Id.*

28. CMS has implemented regulations that state:

> (2) Price concessions.
>
> > (i) In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions. Price concessions include the following types of transactions and items:
> >
> > > (A) Volume discounts.
> > > (B) Prompt pay discounts.
> > > (C) Cash discounts.
> > > (D) Free goods that are contingent on any purchase requirement.
> > > (E) Chargebacks and rebates (other than rebates under the Medicaid program).
> >
> > (ii) For the purposes of paragraph (a)(2)(i), bona fide services fees are not considered price concessions.

42 C.F.R. § 414.804(a)(2).

29. The regulations define BFSFs as follows:

> Bona fide service fees means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

42 C.F.R. § 414.802.

30. CMS requires manufacturers to submit ASP reports no later than thirty days after the close of the previous quarter. 42 C.F.R. § 414.804(a)(5). At times, Medicare payments for Part B drugs have been reduced by 2% due to budget sequestration. *See* Cong. Research Serv., R45106, *Medicare and Budget Sequestration* (Updated November 2023), https://crsreports.congress.gov/product/pdf/R/R45106; HHS Office of Health Policy, *Medicare Part B Drugs: Trends in spending and Utilization, 2006-2017*, Issue Brief HP-2020-02, n.10 (November 2020), https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf ("The sequestration reduces benefit payments by 2 percent from April 1, 2013 through April 30, 2020 and January 1, 2021 through March 31, 2030 and by 4 percent from April 1, 2030 through September 30, 2030. Under the sequester, Medicare payments to providers, but not beneficiary coinsurance payments, are reduced by 2 percent. After applying this payment reduction, the payment rate under the 2 percent sequester is effectively ASP+4.3%. (In other words, as the sequester applies to federal payment only (80 percent of total payment while beneficiaries still pay the full 20 percent copay), the effective federal payment under ASP+6% is reduced to ASP+(1.06*(1-2%*80%))) or ASP+4.3%.)").

III. History Of ASP Methodology

31. Before the introduction of the ASP methodology in 2004, Medicare Part B reimbursed Part B drugs at 95% of the drug's Average Wholesale Price ("AWP"). Unlike ASP, there were "no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer." *Program Payments Should Reflect Market Prices: Hearing Before the Subcomm. on Health and the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 107th Cong. 2 (2001) (Statement of William J. Scanlon), at 2. Instead, AWP represented the manufacturer's suggested "sticker" or "list" price based on self-reported data and did not have to correspond to a market-based transaction price. *Id.* at 4.

32. The increasing costs of pharmaceutical drugs to the Medicare Part B program caused both governmental and non-governmental entities to scrutinize the government's payments systems for those products. This scrutiny revealed flaws with the AWP payment methodology. Among other issues, pharmaceutical manufacturers' AWPs were often "significantly higher than the providers' actual acquisition costs," because, among other things, the government did not require manufacturers to deduct discounts offered to providers from the AWP. Dawn M. Gencarelli, *Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?*, National Health Policy Forum, Issue Brief No. 775 (June 7, 2002), https://www.ncbi.nlm.nih.gov/books/NBK561162, at 5. A study found a "wide range of unknown prices being paid for prescription drugs by providers, who are then reimbursed a fixed amount by Medicare, leading to widely varying profit margins for different doctors." *Id.* As then-Inspector General for HHS testified before the Senate Committee on Finance on March 14, 2002:

> Our reports have shown time after time that Medicare pays too much for drugs. Why does Medicare pay so much? We believe that it is because Medicare's payment methodology is fundamentally flawed. By statutory requirement, Medicare's payment for a drug is equal to 95 percent of the drug's average wholesale price (AWP). However, the AWPs which Medicare uses are not really wholesale prices.

See Reimbursement and Access to Prescription Drugs Under Medicare Part B: Hearing Before the S. Subcomm. on Health Care, 107 Cong. 3 (2002) (Statement of Janet Rehnquist).

33. "Indeed, some doctors began to refer to 'AWP' as 'ain't what's paid.'" *In re Pharm. Indus. Average Wholesale Price Litig.*: 491 F. Supp. 2d 20, 30, (D. Mass. 2007) (Saris, J.), aff'd, 582 F.3d 156 (1st Cir. 2009).

34. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), which replaced the Medicare Part B AWP reimbursement

framework with the ASP framework that remains in place today. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 177 Stat 2066. The MMA provided for a shift from 95% of AWP to 85% of AWP in 2004 and then to 106% of "average sales price" in 2005. *See* 42 U.S.C. §§ 1395u(o)(1)(D)(i), 1395w-3a(b)(1).

35. In April 2004, CMS issued an "interim final rule with comment period" on how manufacturers should calculate ASP for Medicare Part B drugs, and the provision in 42 C.F.R. § 414.804 regarding price concessions mirrored the enumerated types of discounts listed in 42 U.S.C. § 1395w–3a(c)(3). 69 Fed. Reg. 17935, 17938 (Apr. 6, 2004); 42 C.F.R. § 414.804(a)(2) (2004) ("In calculating the manufacturer's average sales price, a manufacturer must deduct the following types of transactions and items: (i) Volume discounts. (ii) Prompt pay discounts. (iii) Cash discounts. (iv) Free goods that are contingent on any purchase requirement. (v) Chargebacks and rebates (other than rebates under the Medicaid drug rebate program).").

36. In August and December 2006, respectively, CMS proposed and implemented the current regulations that require manufacturers to report all price concessions and state that BFSFs are not considered price concessions for ASP price reporting purposes. 71 Fed. Reg. 48982, 49082 (Aug. 22, 2006); 71 Fed. Reg. 69624, 69787 (Dec. 1, 2006). The proposed and final rule also added the definition of BFSFs to 42 C.F.R. § 414.802. *Id.*

IV. The False Claims Act

37. The FCA provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties

> Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

38. For purposes of the FCA, the terms "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. *Id.* § 3729(b)(1).

39. The FCA defines the term "claim," in pertinent part, as

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

Id. § 3729(b)(2).

40. The statute defines the term "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4).

Factual Allegations

I. Eylea's Launch Into The Wet AMD Market

A. Anti-VEGF Market For Wet AMD

41. Neovascular Age-Related Macular Degeneration, commonly known as Wet AMD, is a prevalent, progressive retina degenerative macular disease that leads to gradual vision impairment and mainly affects the elderly. The most common treatment for Wet AMD is the administration of anti-vascular endothelial growth factor ("anti-VEGF") treatments. Anti-VEGF

treatments also have been approved and used to treat other ophthalmological conditions as well, such as diabetic macular edema.

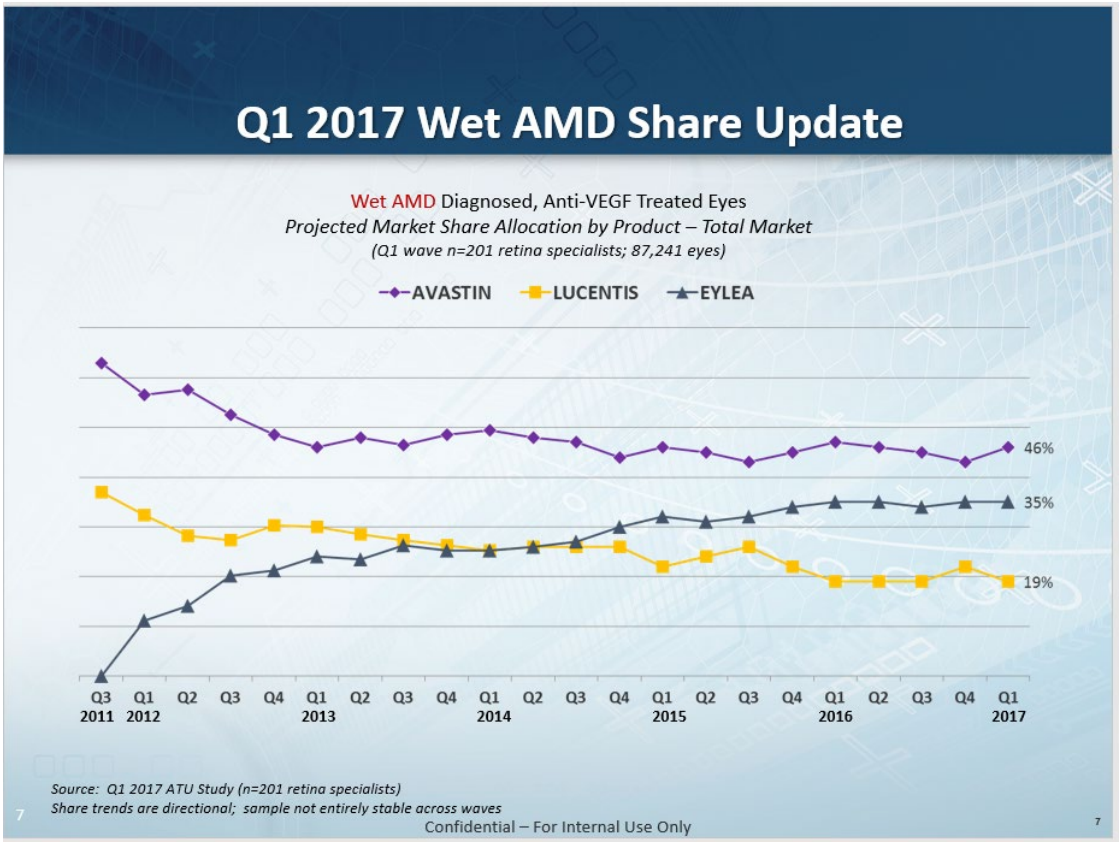
42. In November 2011, the FDA approved Eylea as an anti-VEGF inhibitor for the treatment of Wet AMD. At the time of Eylea's commercial launch into the Wet AMD market, Eylea had two primary anti-VEGF competitor drugs: Avastin and Lucentis, both manufactured by Genentech. Avastin and Lucentis are both anti-VEGF drugs, but while FDA has approved Lucentis to treat various eye conditions, including Wet AMD, Avastin is only approved to treat certain types of cancer. Regeneron announced the commercial launch of Eylea on November 21, 2011, soon after Eylea received FDA approval.

43. Although Genentech has never sought FDA approval of Avastin for Wet AMD, "[o]phthalmologists generally consider all three [Lucentis, Eylea, and Avastin] to be safe and effective treatments for retinal disease." *Anti-VEGF Treatments*, American Academy of Ophthalmology (July 26, 2023), https://www.aao.org/eye-health/drugs/anti-vegf-treatments (citing CATT Research Group, *Ranibizumab and Bevacizumab for Neovascular Age-Related Macular Degeneration* 364 New Engl. J. Med. 1897-1908 (2011); J Clay Bavinger, *et al*., *Comparative Risk of Endophthalmitis After Intravitreal Injection with Bevacizumab, Aflibercept, and Ranibizumab*, 39 Retina. 2004-2011 (2019). Indeed, doctors have submitted, and Medicare has reimbursed, millions of claims for the administration of Avastin for use in the eye.

44. Lucentis and Eylea are substantially more expensive than Avastin per dose when used to treat Wet AMD or diabetic macular edema. Avastin vials are converted (typically by a compounding pharmacy) from the doses sold for cancer treatments (100mg or 400mg) into smaller doses (1.25mg) for Wet AMD. *See, e.g.*, HHS-OIG, *Medicare Payments for Drugs Used to Treat Wet Age-Related Macular Degeneration*, p. 3 (April 2012),

https://oig.hhs.gov/oei/reports/oei-03-10-00360.pdf. When used for ophthalmological purposes, a dose of Avastin costs a fraction as much as a dose of Eylea or Lucentis. Medicare beneficiaries also have a correspondingly lower co-pay for such injections.

45. According to a Regeneron analysis, Eylea surpassed Lucentis's market share by the end of 2014, while Avastin remained the most popular anti-VEGF treatment through at least 2016:



Ex. 1 at Slide 7.

B. Distribution Of Anti-VEGF Drugs For Wet AMD

46. When Regeneron launched Eylea, it opted against selling the drug directly to retina practices. Instead, it contracted with distributors and sold Eylea to them at its wholesale acquisition cost ("WAC"), which was $1,850 per vial. Regeneron paid a fee to those distributors for services related to the distribution of Eylea, including "Customer Service," "Warehouse &

Distribution," "Returns Management," "Finance," "Information Technology & Reporting," and "Chargeback Management." Ex. 2 at "Exhibit D" (2011 Besse Distribution Services Agreement); Ex. 3 at "Exhibit D" (2014 CuraScript Distribution Services Agreement); Ex. 4 at "Exhibit D" (2011 McKesson Distribution Services Agreement). Under its agreements with Besse, CuraScript, and McKesson, Regeneron paid a distribution fee of [redacted] *See id* "Exhibit D" (2011 Besse Distribution Services Agreement); "Exhibit D" (2014 CuraScript Distribution Services Agreement); "Exhibit D" (2011 McKesson Distribution Services Agreement).

47. Distributors then sold Eylea to retina practices. Under the distribution agreements between Regeneron and distributors, Besse and the other distributors were responsible for collecting payments from retina practices. Section 2.3 of the distribution agreements stated: "Customer Contracts. Except as otherwise set forth herein, [Distributor] is responsible for the terms and conditions of any purchase contracts it enters into with customers." Ex. 2 at § 2.3 (2011 Besse Distribution Services Agreement); Ex. 3 at § 2.3 (2014 CuraScript Distribution Services Agreement); Ex. 4 at § 2.3 (2011 McKesson Distribution Services Agreement). Distributor responsibilities related to payment collection listed under the Besse contract specifically included:

- "Accounts Receivable Management - aggregation of customer payments, risk management, etc."
- "Invoicing"
- "Collections Management"

Ex. 2 at "Exhibit D" (2011 Besse Distributor Services Agreement).

48. Regeneron paid distributors a service fee for each unit of Eylea they sold. *See, e.g.,* Ex. 2 at "Exhibit D" (2011 Besse Distribution Services Agreement) ("SERVICES & PRICING . . . Bona fide service fee of [redacted] (the 'Service Fee')"); *see also* Ex. 5 at

"Exhibit D" (2015 Besse Distribution Services Agreement) ("SERVICES & PRICING . . . Bona fide service fee of [redacted] (the 'Service Fee')").

49. Regeneron then paid distributors a *separate amount* for credit card processing fees so that they would not charge retina practices more to use credit cards to purchase Eylea. Section 2.7 of the 2011 Besse distribution agreement between Regeneron and Besse included the following language:

> Credit Card Processing. Distributor agrees to accept credit card payments from customers for Product purchased from Distributor. Subject to Applicable Law, Distributor will pass through all processing charges incurred by Distributor from credit card sales to Regeneron on a monthly basis: These fees will be invoiced by Distributor and paid by Regeneron in the same manner as other fees for Services under this Agreement.

Id. at § 2.7 (2011 Besse Distribution Services Agreement).

50. Section 2.6 of the 2011 distribution agreement between Regeneron and CuraScript included similar language:

> Payment Processing. Distributor agrees to accept payments from customers within the predefined customer terms for Product purchased from Distributor. If customers cannot pay via cash, subject to Applicable Law, Distributor will pass through at average documented cost all related non-cash payment processing charges incurred by Distributor from credit card sales to Regeneron on a monthly basis. These fees will be invoiced by Distributor and paid by Regeneron in the same manner as other fees for Services under this Agreement.

Ex. 6 at § 2.6 (2011 CuraScript Distribution Services Agreement).

51. Section 2.6 of the 2011 distribution agreement between Regeneron and McKesson contained similar language:

> Credit Card Processing. Distributor agrees to accept credit card payments from customers for Product purchased from Distributor only upon receipt of prior written authorization from Regeneron. If so authorized, subject to Applicable Law, Distributor will pass through all processing charges incurred by Distributor from credit card sales to Regeneron on a monthly basis. These fees will be invoiced by Distributor and paid by Regeneron in the same manner as other fees for Service under this Agreement.

Ex. 4 at § 2.6 (2011 McKesson Distribution Services Agreement).

C. Anti-VEGF Economics For Retina Practices

52. Regeneron knew customers tracked their spreads on high-cost, buy-and-bill drugs like Eylea. Large retina practices often have non-medical staff, frequently called "practice administrators," who are responsible for financial aspects of the practice, including tracking their practice's spreads for Eylea, Lucentis, and Avastin. Regeneron hired a number of these practice administrators as consultants and as speakers for Eylea reimbursement-focused dinner events with customers and potential customers.

53. Anti-VEGF drugs, particularly Eylea and Lucentis, were a large portion of retina practices' total office revenues in many cases totaling tens of millions of dollars per year, and profits, in many cases totaling millions of dollars per year. Retina and ophthalmology practices depended on those revenues and profits, and the money they made from reimbursements for Eylea and Lucentis made them attractive acquisition targets for private equity funds. *See, e.g.*, Chen Y *et al., Private Equity in Ophthalmology and Optometry*, 127 Ophthalmology 445, 452 (2020) ("Rising interest in retina practices may also represent [private equity] interest in the potential high net income from increasing use of intravitreal injections and associated imaging reimbursements. In a study of 2013 Medicare reimbursements, ranibizumab [(Lucentis)] and aflibercept [(Eylea)] accounted for nearly 95% of all ophthalmology drug reimbursements."); Singh Y *et al., Increases in Medicare Spending and Use after Private Equity Acquisition of Retina Practices*, 131 Ophthalmology 150 (2024) ("Conclusions: Private equity acquisition of retina practices are associated with modest increases in the use of higher-priced anti-VEGF drugs like aflibercept [(Eylea)], leading to higher Medicare spending.").

54. To understand their expected profit from expensive and often lucrative buy-and-bill drugs, including Eylea, many customers tracked their anticipated revenue and margins on these drugs. Regeneron knew these financial considerations were important to customers and even tracked them itself. For example, in a slide called "Q2 2016, Current Day, Practice Economics," from an internal 2016 presentation, Regeneron calculated "Cost Recovery per Vial" for Eylea, Avastin, and Lucentis, showing that customers had an $80 "Cost Recovery per Vial" for Eylea, not including any credit card rewards or cash back, compared to $20 for Avastin:

Q2 2016, Current Day, Practice Economics

Product	WAC	Physician Purchase Price[1]	Max Rebate[2]	Physician Net Cost w/ Discount & Rebate[3]	Q216 Medicare Payment (ASP +4.3%) Sequestration[4]	Cost Recovery per Vial
EYLEA	$1850	$1850	-	-	$1930	**$80**
Lucentis 0.5	$1950	$1862	-	-	$1901	**$39**
Lucentis 0.3	$1170	$1117	-	-	$1140	**$23**
Avastin	$67	$50	-	-	$70	**$20**

Ex. 7 at slide 5.

55. Regeneron even knew that some practices specifically based their selection of anti-VEGF drugs in part on which drug could provide the greatest profit. *See, e.g.*, Ex. 8, at slides 30, 35 (Regeneron report titled "Biosimilar Value Proposition Exploratory Research," dated December 9, 2020, stating "A few retina specialists (especially in large private [retina specialist] groups) prioritize profit as they make their treatment decisions" and that "[a] small number of retina treaters are highly profit driven" and "factor in carrying costs, *credit card cash-back benefits* & reimbursement schemes for private & government payors" (emphasis added)).

56. When tracking expected spreads, many customers included the amounts that they expected to receive from credit card cash back rewards, listing these amounts in internal documents as a "Credit Card Rebate" or similar term.

57. Because of the high cost of Eylea, this cash back often amounted to hundreds of thousands of dollars per practice per year. One Massachusetts ophthalmic practice tracked its "AMEX Cash Back Earned [] on Amount Paid to Besse" for Eylea purchases on a quarterly basis. Its total cash back on Eylea purchases in 2019 was $445,044.39.

58. In August of 2020, Regeneron employees circulated an investor newsletter containing a transcript of an interview with a practice administrator, who also served as a Regeneron consultant, in which she "explain[ed] rebate and discount dynamics in the market" and disclosed that for "cash back" on credit cards "I think [practices are] doing well if [they] get two percent." Ex. 9, at pp. 1, 8. She noted that as a practice administrator, "At the end of the day, I'm putting all those pieces that I just described to you [(including credit card cash back)] together to look across at margin on that drug." *Id.* at 8.

II. Regeneron Paid Eylea Customers' Credit Card Fees

59. As described above, Regeneron knew that distributors incurred processing fees if retina practices used credit cards to purchase expensive drugs like Eylea, and that, accordingly, distributors would charge retina practices a higher amount to use credit cards for Eylea purchases, unless Regeneron reimbursed those fees. Regeneron also knew that most customers wanted to use credit cards for their expensive drug purchases, in part because of the lucrative cash back rewards. Regeneron thus agreed to, and did pay, the credit card processing fees for retina practices' Eylea purchases.

60. Regeneron leadership, including Chief Executive Officer ("CEO") Dr. Leonard Schleifer, was aware that Regeneron was directly reimbursing its distributors for the credit card fees incurred by the customers' Eylea purchases. In August 2012, Regeneron's Vice President of Financial Planning, Christopher Fenimore, requested Dr. Schleifer's approval of, *inter alia*,

Regeneron's credit card fee reimbursements "so that we can efficiently process the fees payable to Besse and the other distributors." In support of his request, Fenimore wrote:

> The Distributors receive the same service fee of [redacted] for services rendered (i.e., customer service, warehouse and distribution, returns management, finance, information technology and daily reporting, and various other services). The Distributors also pass through credit card fees incurred *when physicians pay for EYLEA with their credit cards*. Credit card fees average approximately two and one-half percent (2.5%), and are expected to be applied to approximately eight-five percent (85.0%) of all orders."

Ex. 10 (emphasis added). Dr. Schleifer responded that the "suggested approach makes good sense. I approve." *Id.*

61. Regeneron executives continued to approve these payments, calling it a "standard practice since 2012" in a subsequent 2017 memorandum:

> As has been standard practice since 2012, the Commercial team and the Strategic Sourcing Department has operated under the rules of an ***approved memo*** being in place as the approval mechanism when making payment to distributors and specialty pharmacies. Regeneron has in place four (4) distributors and nine (9) specialty pharmacies . . . for the distribution of EYLEA. Regeneron has separate Distribution Service Agreements with each of the Distributors and SPs. [redacted], the Distributors receive the same service fee of [redacted] which equates to [redacted], for data and services rendered (i.e., customer service, warehouse and distribution, returns management, finance, information technology and daily reporting, and various other services). . . . The Distributors also pass through credit card fees incurred *when physicians pay for EYLEA with their credit cards* [emphasis added]. Credit card fees average approximately 2.35%, and are expected to be applied to approximately 85.0% of all orders (emphasis added).
>
> …
>
> **[I]ndividual annual Distributor and SP [specialty pharmacy] PO [purchase order] approvals are not required to be approved by the CEO. Instead, an approval memo has documented the CEO's approval for the appropriate POs to be established and approved in accordance with the terms of the individual agreements.** Each month, as the vendor invoices Regeneron, a review and reconciliation is done by the Regeneron Trade Department to assure the invoice amount matches the data/services performed.

Ex. 11 (emphasis in original). The draft approval memorandum to Regeneron's CEO regarding "2021 Distributor & Specialty Pharmacy PO Approvals (EYLEA)" again referred to the "standard practice since 2012" under which "the Commercial team and the Strategic Sourcing Department has [sic] operated under the rules of an *approved memo* . . . ." Ex. 12, at 1. The memorandum stated:

> The Distributors pass through credit card processing fees incurred when physicians pay for EYLEA using a credit cards [sic]. Credit card fees average approximately 2.05% (per recent Finance review) and are expected to be applied to approximately 85% of all orders.
>
> • For 2021, we have adjusted credit card fees based on analysis completed by the corporate Finance teams on actual amounts charged and fees.
> . . .

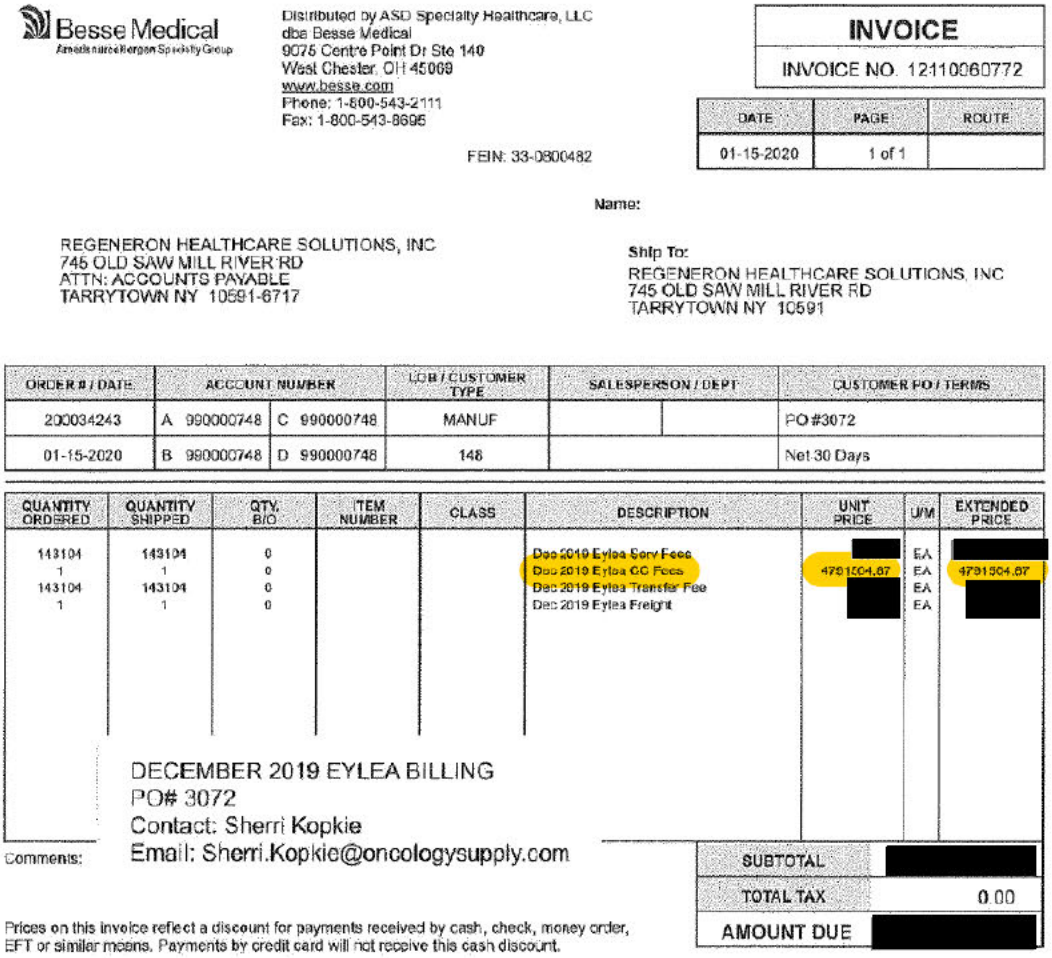
Additional Estimated Fees	Credit Card Fees (as of Q3 2020)	Projected Credit Card Fees
Besse Medical	2.10%	$ 56,903,691
Curascript	2.30%	$ 5,843,383
McKesson Specialty	1.79%	$ 25,858,662
Metro Medical	2.00%	$ 284,091
McKesson Plasma & Biologics		

Id. at 4.

62. Besse and the other distributors provided Regeneron with monthly invoices itemizing the credit card fees on a purchase-by-purchase basis, including the customer, amount of Eylea purchased, and the credit card fee percentage. Besse also provided the actual credit card processing fee amounts incurred for each Eylea purchase. Besse's invoices identified the fees as "EYLEA CR CARD FEES" (or similar), and Regeneron specifically requested backup spreadsheets listing credit card fees on a *per customer* and *per purchase* basis—which Besse provided to Regeneron each month along with its invoices. *See, e.g.*, Ex. 13 (August 2012 internal Regeneron email, forwarding invoice and attachment from Besse, including "EYLEA CR CARD FEES" of $513,815.62, and stating "[a]ttached is the backup info from Besse. I

asked that they send the backup with all invoices.") (exhibit excerpted) (attachments unrelated to credit card fees omitted).

63. Thus, Regeneron understood exactly how much it was paying for Eylea credit card processing fees each month, which was often millions of dollars. For example, a December 2019 invoice from Besse shows "Dec 2019 Eylea CC Fees" of $4,791,504.87:



Besse Medical
An Amerisource Bergen Specialty Group

Distributed by ASD Specialty Healthcare, LLC
dba Besse Medical
9075 Centre Point Dr Ste 140
West Chester, OH 45069
www.besse.com
Phone: 1-800-543-2111
Fax: 1-800-543-8695

FEIN: 33-0800482

INVOICE

INVOICE NO. 12110060772

DATE	PAGE	ROUTE
01-15-2020	1 of 1	

Name:

REGENERON HEALTHCARE SOLUTIONS, INC
745 OLD SAW MILL RIVER RD
ATTN: ACCOUNTS PAYABLE
TARRYTOWN NY 10591-6717

Ship To:
REGENERON HEALTHCARE SOLUTIONS, INC
745 OLD SAW MILL RIVER RD
TARRYTOWN NY 10591

ORDER # / DATE	ACCOUNT NUMBER		LOB / CUSTOMER TYPE	SALESPERSON / DEPT		CUSTOMER PO / TERMS
200034243	A 990000748	C 990000748	MANUF			PO #3072
01-15-2020	B 990000748	D 990000748	148			Net 30 Days

QUANTITY ORDERED	QUANTITY SHIPPED	QTY. B/O	ITEM NUMBER	CLASS	DESCRIPTION	UNIT PRICE	U/M	EXTENDED PRICE
143104	143104	0			Dec 2019 Eylea Serv Fees	[redacted]	EA	[redacted]
1	1	0			Dec 2019 Eylea CC Fees	4791504.87	EA	4791504.87
143104	143104	0			Dec 2019 Eylea Transfer Fee	[redacted]	EA	[redacted]
1	1	0			Dec 2019 Eylea Freight		EA	

DECEMBER 2019 EYLEA BILLING
PO# 3072
Contact: Sherri Kopkie
Email: Sherri.Kopkie@oncologysupply.com

Comments:

SUBTOTAL	[redacted]
TOTAL TAX	0.00
AMOUNT DUE	[redacted]

Prices on this invoice reflect a discount for payments received by cash, check, money order, EFT or similar means. Payments by credit card will not receive this cash discount.

Ex. 14, at 2 (January 2020 email from Besse to Regeneron and attachments titled "Eylea Invoice.pdf" and an excerpt of "Eylea CC Fees 12-19.xls") (highlighting added; attachments unrelated to credit card fees omitted). The backup "Eylea CC Fees 12-19.xls" attachment shows the following:

1/3/2020	Credit Card Payments - Eylea							
SoldToBP	SoldToBPCdDesc	ARDocN	DocDate	ItemCdDesc	OrigTsxA	Item Tot	CC Fee	Fee Amount
000028756	SPRINGFIELD CLINIC LLP	13912289	12/24/2019	EYLEA 2MG VL KIT	-329,011.91	332,167.50	2.72%	$-8,946.11
000028756	SPRINGFIELD CLINIC LLP	13887654	12/11/2019	EYLEA 2MG KIT	-325,438.68	328,560.00	2.72%	$-8,848.95
000106959	VITREORETINAL SURGERY PA	13792922	12/31/2019	EYLEA 2MG KIT	-499,979.52	490,176.00	1.70%	$-8,499.65
000110901	CAPE FEAR RETINAL ASSOCIATES	13745938	12/18/2019	EYLEA 2MG KIT	-355,200.00	355,200.00	2.31%	$-8,193.77
000062286	EYECARE MEDICAL GROUP	13794860	12/24/2019	EYLEA 2MG KIT	-348,984.00	355,200.00	2.31%	$-8,050.38
000062308	RETINA ASSOCIATES OF MISSOURI	13725076	12/03/2019	EYLEA 2MG KIT	-340,992.00	340,992.00	2.31%	$-7,866.02
000062308	RETINA ASSOCIATES OF MISSOURI	13766959	12/09/2019	EYLEA 2MG KIT	-334,683.65	340,992.00	2.31%	$-7,720.50
000062308	RETINA ASSOCIATES OF MISSOURI	13776733	12/09/2019	EYLEA 2MG KIT	-334,683.65	340,992.00	2.31%	$-7,720.50
000062308	RETINA ASSOCIATES OF MISSOURI	13740251	12/03/2019	EYLEA 2MG KIT	-334,683.65	340,992.00	2.31%	$-7,720.50
000062225	ROCKY MOUNTAIN RETINA CONS	13829442	12/19/2019	EYLEA 2MG KIT	-301,920.00	301,920.00	2.31%	$-6,964.70
000063327	CINCINNATI EYE INSTITUTE	13815844	12/13/2019	EYLEA 2MG KIT	-255,744.00	255,744.00	2.72%	$-6,953.89
000063327	CINCINNATI EYE INSTITUTE	13804473	12/10/2019	EYLEA 2MG KIT	-255,744.00	255,744.00	2.72%	$-6,953.89
000063327	CINCINNATI EYE INSTITUTE	13807657	12/13/2019	EYLEA 2MG KIT	-255,744.00	255,744.00	2.72%	$-6,953.89
000063327	CINCINNATI EYE INSTITUTE	13810111	12/13/2019	EYLEA 2MG KIT	-255,744.00	255,744.00	2.72%	$-6,953.89

Id. at '510 (spreadsheet excerpted, sorted by "Fee Amount," and highlighted).

64. Like Besse, McKesson and CuraScript invoiced Regeneron monthly for credit card fees and provided an itemized list of the credit card fees Regeneron was paying on a purchase-by-purchase basis. Regeneron also used the transaction-level detail to analyze McKesson and CuraScript invoices for credit card fees. For example, a June 2017 internal Regeneron email stated, "Attached is the credit card fee analysis for McKesson and CuraScript." The attachment, "McKesson Specialty CC Fees Analysis – V2.xlsx" and "CSD CC Fees – V2.xlsx," showed monthly credit card bills by company—over $9.5 million in credit card fees on over $387 million in Eylea sales through McKesson between July 2016 and March 2017 and over $8 million in credit card fees on over $341 million in Eylea sales through CuraScript between July 2016 and March 2017. Ex. 15 (attachment excerpted). The attachment also provided transaction-level data. *Id.*

65. Regeneron approved distributors' invoices for credit card fees. *See, e.g.*, Ex. 16 (internal March 2018 Regeneron email stating that Besse invoices, including "EYLEA CR CARD FEES" of $2,370,026.95, "have been validated and approved for payment."); Ex. 17 (internal Regeneron email forwarding Besse July 2015 invoice for "EYLEA CR CARD FEES" of $2,333,062.35 and excerpted backup "Eylea CC Fees 07-15.xls" and confirming the "July

2015 invoices match the validation report and can be . . . processed."); Ex. 18 (February 2016 Regeneron email approving December 2015 invoice with "EYLEA CR CARD FEES" of $2,460,411.94 sent with excerpted transaction data attachment "Eylea CC Fees - 12-15.xls").

66. Regeneron and the distributors also took steps to ensure that the credit card fee invoices accurately reflected the actual credit card processing fees on customers' Eylea purchases, and at times the distributors submitted modified or amended invoices that Regeneron agreed to pay. *See, e.g.*, Ex. 19 (internal September 2012 Regeneron email with the subject "Eylea CC Fees 08-12 (Besse).xlsx" noting "The credit card invoice is okay to approve. There were mistakes in the first 10 lines which caused us to be overbilled by $1200. Besse will be issuing a credit memo for the overcharge.") (attachment excerpted); Ex. 20 (email approving November 2016 "EYLEA CR CARD FEES" of $2,128,162.15 that were adjusted to reflect prior overbilling on certain April and May 2016 transactions, as detailed in the excerpted "Eylea CC Fees 11-16.xls" attachment); Ex. 21 (internal December 2016 Regeneron email concerning a CuraScript request to lower credit card fees charged from 2.5 percent to 2.4 percent to reflect "their actual credit card fees[.]").

67. Regeneron closely monitored the credit card fee payments. Rena Goins, then Regeneron's Executive Director of Global Trade, GPO & Distribution, sent an internal email stating: "Team, I have some important questions about credit card pass through fees with our specialty distributors on EYLEA. . . . I firmly believe we are entitled to more insight and granularity on these details from the SDs [(specialty distributors)] because we allow them to pass the fee back to us." Ex. 22, at 2. Regeneron's Director of Trade Relations responded to the email chain with a chart that included breakdowns of credit card purchases and fees at each specialty distributor:

	Besse	McK	MPB	Curascript	Metro	Cardinal SPD
For each SD what is % of credit card sales as % of total sales for that SD?	2019 average was 70.4%	74% YTD 2020	N/A	2019 average was 68%; similar for 2020 YTD	Too early for meaningful data. Only 3 accounts	No credit card transactions; all hospital based
What is the credit card fee – ACTUAL %s passed through or a flat % for the fees they pass through	2019 average was 2.08%	Q1/Q2 '20: 1.69% Avg.	N/A	2.3%		
Do we know if fee is for VISA, MasterCard or AMEX?	**Average – Q2/2020** AMEX – 38% Visa – 39% MC – 32% Discover -	AMEX: 73% MC: 3% VISA: 24%	N/A	Average 53% AMEX 33% VISA 13% Mastercard 1% Discover		

Id. at 1.

68. The amount Regeneron paid for the credit card processing fees grew over time. For example, in the first quarter of 2014, Regeneron paid Besse approximately $1.5 million per month, with a total of $4.6 million to Besse and $5.4 million in credit card processing fees to all of Regeneron's specialty distributors for the quarter:

	January-14	February-14	March-14	Q1-2014 Total	YTD Total
Sales:					
Mckesson Plasma & Biologics LLC	2,619,600	6,127,200	7,237,200	15,984,000	15,984,000
Mckesson Specialty Care	13,630,800	13,542,000	10,522,800	37,695,600	37,695,600
ASD Specialty Healthcare (Besse)	100,299,600	101,187,600	105,050,400	306,537,600	306,537,600
Priority Healthcare Dist Inc (CuraScript/Express Script)	3,418,800	5,594,400	7,059,600	16,072,800	16,072,800
Walgreens	1,332,000	1,953,600	1,287,600	4,573,200	4,573,200
Avella Wholesale (Apothecary)	666,000	666,000	666,000	1,998,000	1,998,000
Total Gross Sales:	**121,966,800**	**129,070,800**	**131,823,600**	**382,861,200**	**382,861,200**
Total Gross Vials	65,928	69,768	71,256	206,952	206,952

…

Credit Card Fees: *(Based on 60% of Sales)*					
Mckesson Specialty Care @ 2.5%	204,462	203,130	157,842	565,434	565,434
ASD Specialty Healthcare (Besse) @ 2.5%	1,504,494	1,517,814	1,575,756	4,598,064	4,598,064
Priority Healthcare Dist Inc (CuraScript) @ 2.5%	51,282	83,916	105,894	241,092	241,092
Avella Wholesale (Apothecary) @ 2.5%	9,990	9,990	9,990	29,970	29,970
Total Credit Card Fees	1,770,228	1,814,850	1,849,482	5,434,560	5,434,560

Ex. 23 (internal March 2014 calendar invite and attachment titled "EYLEA Revenue MAR-14.pdf") (second attachment omitted).[4]

[4] In an internal September 2013 email, Robert Davis, then Regeneron's Executive Director and Head of Trade, explained why Regeneron paid credit card fees to Avella but not Walgreens: "Ok although both are Specialty Pharmacies whereas they dispense drug on behalf of insurance

69. Those fees grew to millions of dollars per month (including $7.5 million for December 2020) for Besse alone, as detailed in a June 2021 email exchange and attached presentation titled "Besse Medical – Regeneron Eylea Credit Card Discussion" regarding the increases in invoiced amounts for Eylea credit card fees. Ex. 24, at slide 2.

70. Regeneron's memoranda for approving these invoices also show that Regeneron knew its credit card fee payments were substantial. The 2017 approval memorandum identified that credit card fees were roughly two-thirds of the amount Regeneron paid for all distribution services:

SD Vendor	Current Fees Per Vial (as of Jan 1, 2017)	Which Equates to X% of WAC	Avg Monthly Credit Card Fees (as of Jan 1, 2017)	PAP Fees Per Vial (as of Jan 1, 2017)	2017 Estimated Distribution Payments[1]
Besse Medical[3,4]	[redacted]	[redacted]	2.15%	[redacted]	$105,000,000
McKesson Specialty[2]	[redacted]	[redacted]	2.46%	-	$40,000,000
Curascript[2]	[redacted]	[redacted]	2.42%	-	$28,000,000
McKesson Plasma & Biologics[2]	[redacted]	[redacted]	-	-	$5,936,000
SD Total					**$178,936,000**

Ex. 11, at '122.

71. The 2021 draft approval memorandum identified "Projected Credit Card Fees" of $56.9 million for Besse alone:

Additional Estimated Fees	Credit Card Fees (as of Q3 2020)	Projected Credit Card Fees
Besse Medical	2.10%	$ 56,903,691
Curascript	2.30%	$ 5,843,383
McKesson Specialty	1.79%	$ 25,858,662
Metro Medical	2.00%	$ 284,091
McKesson Plasma & Biologics		

Ex. 12, at '056 (attachment unrelated to Eylea omitted).

companies. Therefore no credit cards accepted. Avella is also an approved distributor so we pay the pass thru CC fees for doctor purchases." Ex. 25, at 2.

72. Regeneron records show that, for the period from January 2018 through May 2021, Regeneron paid Besse, McKesson, and CuraScript over $250 million for credit card processing fees for Eylea.

III. Regeneron's Eylea Credit Card Processing Fee Payments Reduced Customers' Costs To Purchase Eylea

73. An unwritten, but well-understood and followed, component of Regeneron's agreements with distributors was that Regeneron paid credit card processing fees for customers' Eylea purchases *on the condition* that the distributors did not charge Eylea customers more to use a credit card—which Regeneron knew they otherwise would in the absence of Regeneron's payments.

74. Regeneron accordingly paid distributors for the credit card processing fees for Eylea purchases so retina practices could purchase Eylea at the lower cash price from distributors while still reaping the benefits of using credit cards.

75. Besse, for example, used the term "cash discount lost" to refer to the higher amount that its customers paid when they used credit cards instead of cash or a cash-equivalent method. Besse's Vice President of Sales explained to a large retina practice in July 2013, that "we consider all of our pricing to be a cash price" and while "Eylea (Regeneron) can be paid by credit card" without incurring a "cash discount lost fee," Lucentis and Avastin "can NOT be paid by credit card without forfeiting the cash discount (which adds ~2.4% to the cost)." Ex. 26 (capitalization in original).

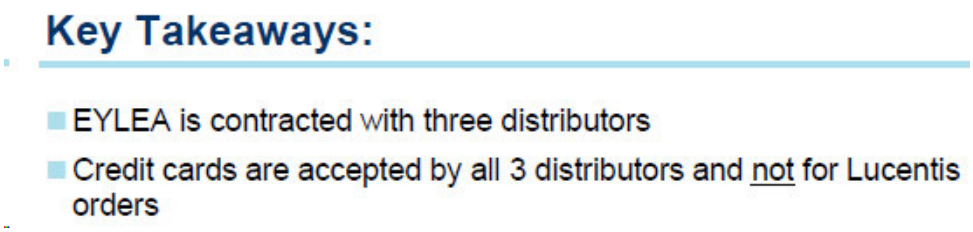
76. Regeneron knew Besse's invoiced prices to customers reflected a "cash discount." Both Besse's invoices to customers and its invoices to Regeneron for "Eylea Cr Card Fees" explicitly stated that the invoiced prices reflected a "cash discount" and that payments by credit card would not receive that discount:

> Prices on this invoice reflect a discount for payments received by cash, check, money order, EFT or similar means. Payments by credit card will not receive this cash discount.

See, e.g., Ex. 14; *see also* Ex. 27 (November 2011 email exchange regarding a "Credit Card Question" from a retina practice about whether distributors impose an "additional charge" to use credit cards to purchase Eylea (noting "with Lucentis they had a 3% charge to get it through Bessie [sic]") to which Regeneron executives responded "No Besse does not pass along those fees to customers" and *"[w]e are covering the credit card pass thru fees.*") (emphasis added).

77. Before and after Eylea's launch, Regeneron understood the competitive nature of the Wet AMD market, including that retina practices were sensitive to the higher prices they faced when they used credit cards to purchase Anti-VEGF medications. In July 2011, a Regeneron "Reimbursement Business Manager" sent an internal email describing this dynamic and noting that it was a "big deal" for certain customers to be able to use credit cards without incurring an additional expense: "Lucentis [D]irect does not charge the providers any more for paying with a credit card, however *the distributors (Besse) do charge more for a credit card payment. This also was a big deal for several accounts*." Ex. 28 (emphasis added). Robert Davis, then Regeneron's Senior Director of Trade, Reimbursement and Managed Markets, responded "Good feedback and pretty consistent . . . . *We will pay pass thru fees so the 3 distributors [(Besse, McKesson, and CuraScript)] will not charge extra to offices*." *Id.* (emphasis added).

78. Regeneron marketed to customers that they could use credit cards to purchase Eylea from distributors without paying more—and that customers could not do so for Lucentis—as a "Key Takeaway" in its messaging:



Ex. 29, at slide 11 (August 2011 internal email with attachment titled "Product Acquisition EYLEA 4U and Marketing messaging and resources").

79. Shortly after Eylea's launch, in February 2012, a Regeneron employee reported to Robert Davis, then Regeneron's Senior Director of Trade, Reimbursement and Managed Markets, that "CuraScript told [a doctor] that [$]1850 was *cash only price*. They added 2.5% for use of credit card use [sic]." Ex. 30 (emphasis added). Mr. Davis forwarded the email to CuraScript employees, noting: "As you know, we cover your cc pass thru costs, see below. Please let me know that this is [or] will be corrected asap." *Id.* Mr. Davis followed up several times, asking "Importance: High[:] ANY UPDATE ON THIS ACCOUNT? My VP is asking me again[,]"and, later, "Reminder: As you know, we cover your credit card pass thru costs[.]" *Id.* After the issue had been resolved and CuraScript had "adjusted the invoice[,]" a Regeneron employee asked Mr. Davis, "Do we know if other accounts that us[e] CuraScript were hit with credit card fees?" *Id.* Mr. Davis responded that "[t]hey are supposed to be adjusting them." *Id.*

80. In August 2012, Relator Nunnelly, then Regeneron's Southeast Regional Sales Director, emailed Mr. Davis, informing him that a large account "is having issues with McKesson. McKesson said if they used AmEx there is an additional 3% charge added to the purchase of Eylea to cover the credit card fees." Ex. 31, at 2. Mr. Davis forwarded this email to a McKesson employee, asking "Can you investigate this case and get back to me as soon as possible. I don't want McKesson [to] lose an account to another distributor." *Id.* Another McKesson employee followed up with Ms. Nunnelly and Mr. Davis stating, "I am not sure who

is giving [the account] the information about the 3% fee, but that is incorrect. They can pay with credit card at 180 day terms *at no charge*." *Id.* at 1 (emphasis added). There was "no charge" because Regeneron paid McKesson for credit card processing fees on Eylea purchases; otherwise, McKesson would have charged customers more.

81. In a September 2012 presentation, Mr. Davis identified "key critical success factors" that led to Eylea's launch becoming "one of the most successful Bio launches ever." Ex. 32, at slide 1. One of those "Critical Factors for a Successful Launch" was a "Solid product distribution network" and Mr. Davis specifically identified: "[u]nderstanding customer acquisition needs, and giving them 180 days dating *and a rewarding credit card program*" in his talking points. *Id.* at slide 3 (speaker notes) (emphasis added). Regeneron was well-aware that the ability to use credit cards was important to customers—which is why Regeneron paid credit card processing fees for Eylea, so customers could reap the benefits of using credit cards without being charged more by distributors.

82. In January 2013, Mr. Davis and other Regeneron employees discussed an email from an American Express employee regarding a doctor who "spends roughly 400K per month . . . on your new drug Eylea. He would like to be able to use his Corporate Card to pay those invoices with you." Ex. 33. Mr. Davis noted internally, including to Bob Terifay, Regeneron's Senior Vice President, Commercial, that the "doctor can use his corporate AMEX to pay for his EYLEA thru Besse, McKesson, CuraScript or Avella (Apothecary Shop)." *Id.* Mr. Davis later reported he "just spoke with the AMEX rep and we are all set." *Id.*

83. In May 2013, Regeneron retained Charles River Associates ("CRA") to conduct market research concerning, among other things, the "clinical and economic landscape of Lucentis and EYLEA at ophthalmology clinics." Ex. 34, at slide 3. CRA collected feedback

from retina practices that demonstrated that "[t]he ability to order using credit cards was seen as important[.]" *Id.* at slide 41. As one practice noted, "[w]e make every purchase with our credit card and the rewards we earn there is pretty important." *Id*. Another practice noted that "[t]he ability to take advantage of our credit card rewards is very important to us and you may find that true for many." *Id*. at slide 23.

84. Mick Besse, Besse's CEO, explained in a July 2013 email sent internally within Besse's parent company, AmerisourceBergen Corporation ("ABC"):

> The Lucentiis [sic] Direct program continues to be a very challenging program for Besse, as the direct discount exceeds our total combined distribution discount and fees and *the customer has the ability to use a credit card*, which would force us to incur an additional cost to match (1.8 to 2.5% bank fees), *so obviously the Direct program is something we cannot compete with in a meaningful way*. *We play a necessary evil role for Genentech in that we offer a way for physician customers who do not want to or cannot use a credit card to purchase* (we offer extended dating beyond our terms as a way to compete) and we also service non-physician accounts (hospital owned practices and facilities, SPP's) who cannot buy thru the Direct program. Clearly, these accounts are buying from us out of necessity, as they are foregoing a significant discount that also serves to drag down the ASAP [sic].

Ex. 35, at 2 (emphasis added). Besse's CEO also noted "I need to be very, very careful not to turn Regeneron against us, as they clearly believe that they are fighting Genentech 'with us', so I need to approach this carefully." *Id.* at 1.

85. Regeneron marketed the ability for customers to use credit cards without incurring an additional surcharge. In October 2015, one of Regeneron's paid speakers, a practice administrator for a retina group in Colorado, emailed Regeneron's Associate Director of Market Access-Ophthalmology with the subject line "I heard…" and continuing in the body of the message, "[t]hat Besse is charging 2% on credit card purchases. Do we disclose?" Ex. 36, at 2. Regeneron's Associate Director forwarded this email to Robert Krukowski, Regeneron's Senior Manager for Reimbursement & Managed Markets Marketing, who responded "Not for EYLEA

maybe for Lucentis *but not for us we pay the credit card fee*." *Id.* at 1 (emphasis added). The Associate Director responded "OK, I'll let her know." *Id.*

86. In November 2015, a Regeneron Medical Specialist wrote an internal email to Mr. Davis and others, noting a customer's "concern about Besse . . . . He told me that credit card payments to Besse incur a 3% charge. He is more familiar with ordering Lucentis and they do not charge 3% so this is an issue for him." Ex. 37. Mr. Davis responded: "As for credit card fees there is a misunderstanding there. *We pay credit card fees thru Besse but lucentis* [sic] *thru Besse does not.*" *Id*. (emphasis added).

87. Similarly, Regeneron's "Eylea New Hire Training" slide deck from May 2015 noted: "Doctors can purchase EYLEA from Besse, CuraScript and McKesson with the option to use major credit cards"—*i.e.* without a fee. Ex. 38, at slide 21. However, for Lucentis, "*Genentech does not subside* [sic] *credit card use* thru Besse, McKesson or CuraScript (or any other distributor). Credit card payment options are only available through *Lucentis Direct." Id.* (emphasis added).

88. A 2016 email from Robert Besse, then Vice President of Operations at Besse, to other Besse employees references a call from Mr. Davis regarding a customer who "called the CEO at Regeneron to complain that we were not giving him a discount and were coding his credit cards wrong. Bob asked we look into it and I need to pass this on." Ex. 39. Mr. Davis followed up again approximately two weeks later "to see if anyone reached out" to the customer. *Id.* Regeneron, including its most senior management, knew that customers valued the ability to pay for Eylea with a credit card while being charged the lower cash price.

89. A September 2018 presentation sent to Regeneron's CEO, titled "EYLEA Provider Discounting and Pricing Strategy" noted "Research confirmed that cost recovery is a

key factor in practice decision making in light of limited perceived clinical differentiation in anti-VEGF . . . Majority of physicians receive credit card points on anti-VEGF purchases, limiting the appeal of discounts[.]" Ex. 40, at slide 11.

IV. Regeneron Knowingly Submitted False ASP Reports For Eylea To CMS And Inflated Eylea's Reported ASP

90. Regeneron knew its payments of credit card processing fees were price concessions and not BFSFs, and yet failed to include them as price concessions in its Eylea ASP reports. As a result, Regeneron artificially inflated Eylea's ASP (and therefore Medicare's reimbursement rates for Eylea) in the ASP reports it submitted to CMS.

A. Regeneron Knew Its Credit Card Processing Fee Payments Were Price Concessions That Did Not Meet the Definition of BFSFs

91. Regeneron understood that payments from a manufacturer that lower a customer's cost to purchase a drug are price concessions for ASP purposes—and thus the manufacturer (Regeneron) is required to deduct them from ASP reporting—unless they met the following four-part regulatory definition of a BFSF: (i) a fee paid by a manufacturer to an entity that represents fair market value (ii) for a bona fide, itemized service actually performed on behalf of the manufacturer (iii) that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and (iv) that are not passed on in whole or in part to a client or customer of an entity. 42 C.F.R. § 414.802.

92. As set forth in Regeneron's "Bona Fide Service Fees and VA Service Fees Evaluation Standard Operating Procedure" ("BFSF SOP"), effective April 1, 2016, Regeneron knew each service fee must be evaluated against this four-part BFSF definition, which Regeneron referred to as "CMS' 4-Part BFSF Test," in order "to determine if the fee is for a type of service that could be a BFSF *or rather is a price concession or discount*." Ex. 41, at § 5.4.1.1.1 (emphasis added).

93. As alleged herein, Regeneron knew that its payments to distributors for credit card processing fees on Eylea purchases lowered the price Eylea customers paid for the drug, and therefore constituted price concessions. *See* ¶¶ 73-89. Rather than reporting them as price concessions, however, Regeneron attempted to disguise the credit card processing fee payments as BFSFs, when it knew that those fees failed to qualify under the four-part BFSF definition. Specifically, as detailed further below, Regeneron knew that its payment of the credit card processing fees: (i) was not a bona fide, itemized service actually performed on Regeneron's behalf; (ii) was not a service Regeneron would otherwise perform or contract for; and (iii) was passed on to Eylea customers. As such, Regeneron's knew its failure to report its payment of credit card fees as price concessions was false or fraudulent.

i. Regeneron Understood That Payment Of Credit Card Processing Fees Was Not A Bona Fide, Itemized Service That Was Actually Performed On Regeneron's Behalf

94. Under the Eylea distribution agreements, Regeneron paid distributors a fee to render the various distribution services. The credit card processing fee was separate and distinct from the distribution fee, indicating that it was not, in fact, compensation for bona fide distribution services. *See* ¶¶ 46-51*, supra.* There was no additional service performed by distributors for this additional amount, which only served to lower the cost of Eylea for customers who wanted to use credit cards.

95. In effect, the "service" at issue was to pay distributors to accept credit cards *without charging customers more*. Indeed, while Regeneron's agreements with distributors omitted this key provision of the arrangement, Regeneron zealously enforced it as described herein. *See* ¶¶ 73-89*, supra.*

96. Indeed, Regeneron knew that distributors would have accepted credit cards for Eylea without these payments and would simply have charged customers more. Regeneron also knew that distributors did not need to accept credit cards (with or without a fee) in order to distribute Eylea. As such, Regeneron expressly knew that the purported "service" of enabling distributors' "acceptance of credit cards without a fee" was not a type of service a manufacturer needed to perform.

97. Moreover, this "service" was performed on behalf of customers—not Regeneron. Under the distribution agreements, distributors already contracted with Regeneron to obtain payment from customers for Eylea purchases. *Supra* at ¶¶ 46-51. And yet, Regeneron paid the distributors a separate fee to cover credit card processing fees *to cause distributors to accept credit cards for Eylea purchases without charging customers more to do so*. Regeneron knew that these payments were made on behalf of customers—*not* for services "on behalf of the manufacturer" (*i.e.* Regeneron) as required for a BFSF.

98. Indeed, in 2019, Deloitte, acting as a consultant to Regeneron, provided Regeneron with a "final BFSF SOP and BFSF Grid[.]" The "BFSF Grid" contained BFSF analyses, specifically including a work sheet evaluating the service fees Regeneron paid to specialty distributors under the "CMS Four Part [BFSF] Test" and a specific row for "Credit Card Fees[.]" Ex. 42, at '081 (excerpt) (other attachments omitted). In a column titled "TYPE OF SERVICE COULD BE BFSF?," shorthand for whether the service was a bona fide, itemized service on behalf of the manufacturer, Deloitte wrote "No" in the row for credit card fees. *Id.*

ii. Regeneron Understood That Payment Of Credit Card Processing Fees Was Not A Service That Regeneron Would Otherwise Perform Or Contract For In The Absence Of Its Agreements With Distributors

99. Regeneron knew that, in order to qualify as a BFSF, its payment of credit card processing fees needed to be a service "the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement . . ." 42 C.F.R. § 414.802.

100. Accordingly, Regeneron's BFSF SOPs required Regeneron to "Determine whether the fee is for a legitimate service for which Regeneron would otherwise have to perform or contract." Exs. 41 and 42, at § 5.4.1.1.1.2.

101. Regeneron knew it did not have to perform or contract for the "service" of causing distributors to waive costs to customers for using credit cards in order for Eylea to be distributed. Had Regeneron not paid the distributors' credit card processing fees, customers would have paid distributors a higher price to use credit cards for their Eylea purchases or used a different payment method.

102. Indeed, with respect to the credit card processing fees, Deloitte's "BFSF Grid," which it provided to Regeneron, noted "N/A" under the column titled "SERVICES REGENERON WOULD PERFORM?" Ex. 42, at '081 (excerpt) (other attachments omitted).

iii. Regeneron Understood That Credit Card Processing Fees Were Passed On In Whole Or In Part To Eylea Customers

103. As described above, Regeneron was aware that distributors agreed to accept credit cards for Eylea purchases without charging customers more *only if* Regeneron reimbursed the distributors for the cost of the credit card processing fees. Thus, Regeneron's reimbursement of credit card fees was functionally no different than if Regeneron or distributors *directly paid* customers to cover the higher costs they would otherwise have incurred, or if distributors credited customers for those amounts on their invoices, based on Regeneron's payments.

104. Regeneron knew its payments were passed on to customers in two ways: (1) the lower, subsidized prices customers paid when they used credit cards to purchase Eylea from

distributors, and (2) the "cash back" and credit card rewards Eylea customers received from those purchases.

105. Regeneron knew exactly how much it was paying on behalf of each customer for each Eylea purchase. As described above, Regeneron received transaction level data detailing the credit card fee amounts it paid on behalf of customers for each Eylea purchase. *Supra* at ¶¶ 62-65.

106. Regeneron also took steps to ensure that distributors were not charging more to Eylea customers who used credit cards, and that customers accordingly received the benefit of Regeneron's reimbursements. *Supra* at ¶¶ 71-86.

107. The "BFSF Grid" Deloitte sent to Regeneron included a column titled "NOT PASSED THROUGH?" For Eylea credit card fees Deloitte entered "N/A"—while the entries for Regeneron's other specialty distributor fees for Eylea began with "Yes." Ex. 42 at '081.

B. Regeneron's Internal Compliance Documents Demonstrated That Regeneron Knew It Improperly Applied The BFSF Test

108. Regeneron's failure to follow the steps in its own BFSF SOPs for evaluating whether service fees paid to distributors were BFSFs further demonstrates that it knowingly disregarded the four-part BFSF test. Regeneron's BFSF SOPs clearly state that "This Standard Operating Procedure (SOP) describes Regeneron['s]. . . controls, processes and methodology pertaining to its determination of whether a proposed fee constitutes a Bona Fide Service Fee ("BFSF") for Average Manufacturer Price ("AMP"), Best Price ("BP"), and Average Sales Price ("ASP") . . . ." *E.g.,* Ex. 42, at § 1.1.1 (BFSF SOP revised as of January 1, 2019). Regeneron's BFSF SOPs make clear that Regeneron needed to evaluate whether the "fee is for a type of service that could be a BFSF or rather is a price concession or discount." *Id.* at § 5.4.1.1.

Regeneron's BFSF SOPs also cite directly to the language of the four-part BFSF definition and require that each service fee be evaluated against the definition:

> In order to be treated as a BFSF, the service being evaluated must (1) be a bona fide, itemized service that is actually performed on behalf of the manufacturer; (2) be a service Regeneron would otherwise perform or contract for in the absence of the service arrangement; (3) represent fair market value (FMV); and (4) not be passed on in whole or in part to a client or customer of any entity or any other third party.

Exs. 41 & 42, at § 5.4.1.1.

109. Regeneron failed to follow its own BFSF SOPs. In an internal document titled "Regeneron's Reasonable Assumptions" that was "[l]ast updated 4/21/2016," Regeneron purported to assess the credit card fee payments under the four-prong test:

> Based on CMS' 4-Part BFSF Test, Regeneron has concluded that the actual cost of the credit card fees are in-line with common industry terms and does not exceed Fair Market Value (FMV). Therefore, Regeneron considers credit card fees as BFSFs for the calculation of ASP.

Ex. 43, at 25. Rather than analyzing the fees under each of the four prongs, however, the internal reasonable assumptions document appears to have created its own standard concerning "common industry terms," which has no basis in the BFSF four-prong test, and FMV, which represents only a single prong. Applying that baseless "standard," Regeneron allegedly "concluded" that the credit card fee payments were BFSFs.

110. The "Client Approver" for this "conclusion" is listed as Alicia Pantaleo, with a "Client Approval Date" of May 24, 2016. *Id.* Regeneron purportedly required these so-called "client approvers" to sign off on Regeneron's ASP assumptions, including its treatment of credit card fees as BFSFs. But those client approvers, including Ms. Pantaleo, did not perform any BFSF analyses to substantiate Regeneron's "conclusions" prior to approving them.

111. Indeed, two years later, in February 2018, Ms. Pantaleo asked Deloitte, Regeneron's consultant, "did we ever do anything on credit card fees to substantiate that they were BFSF?" Ex. 44.

C. Regeneron Chose Not To Properly Report Its Payments As Price Concessions To Keep Eylea's ASP Stable

112. "Buy-and-bill" drugs like Eylea and Lucentis often face downward pricing pressure when competing products enter the market, as manufacturers offer price concessions to increase customers' spreads on their respective products.

113. Regeneron understood that it was legally obligated to report price concessions to CMS and that doing so would lower Eylea's ASP. A lower ASP meant that a manufacturer needed to offer more price concessions to offer the same spread. Indeed, as Regeneron was aware, Lucentis's ASP declined because Genentech offered and reported rebates for Lucentis (Eylea's primary FDA-approved competitor).

114. Regeneron specifically understood the significance of BFSF determinations to physician reimbursement rates. For example, in February 2013, IPN, a division of AmerisourceBergen Corporation (Besse's parent corporation), gave a presentation to Regeneron, including Robert Davis, titled "IPN - Regeneron Partnership" that explained:

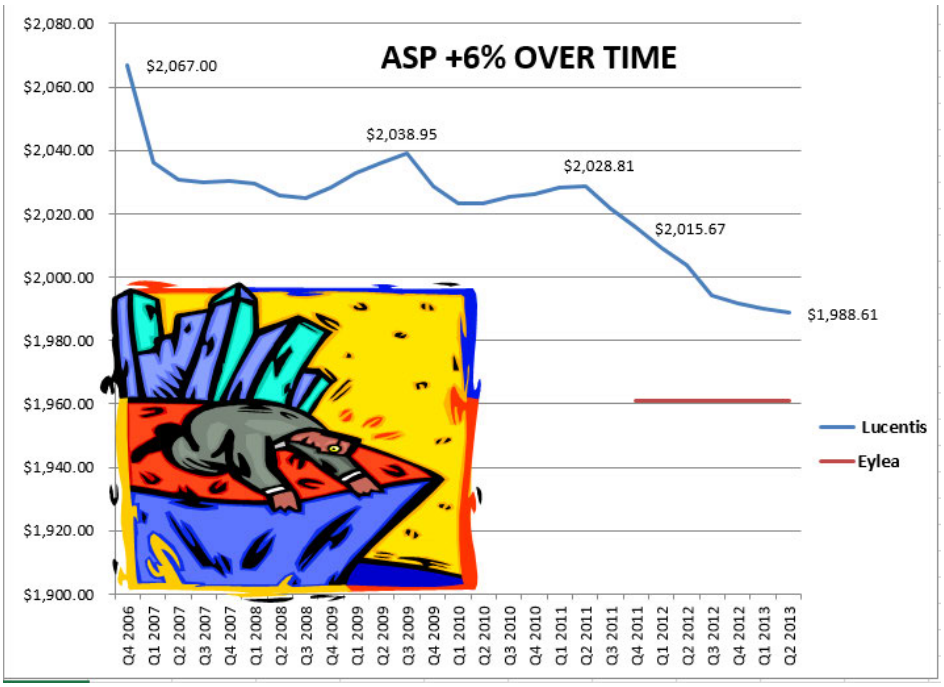
> Pharmaceutical manufacturers are required to report to [CMS] the [ASP] of products they sell. ASP is then used by CMS to calculate reimbursement rates for providers that purchase these products. As a result, what is included or excluded in ASP has a direct effect on physician reimbursement rates.
> Congress and CMS have expressly stated that certain fees paid by manufacturers to third parties may be excluded from ASP ***so long as these fees constitute bona fide service fees***.

Ex. 45, at slide 24 (emphasis added). IPN specifically warned Regeneron that paying certain types of service fees "*will likely result in lower reimbursement for the entire physician market*." *Id.* at slide 25 (emphasis in original).

115. Accordingly, Regeneron falsely characterized its credit card-related payments as BFSFs to keep Eylea's ASP "stable" – and marketed it as more stable than Lucentis's ASP. As Lucentis's ASP dropped, Eylea's reimbursement rate stayed the same into 2017, and then declined only marginally.

116. Regeneron marketed that it did not offer reportable price concessions in order to keep Eylea's ASP stable. *See, e.g.* Ex. 46, at 2 (July 17, 2017 email from Robert Krukowski to Bob Davis containing "Draft FAQ" for "Pricing and Group Purchasing Organizations") ("Regeneron does not currently offer or endorse any discounts or rebates in connection with EYLEA . . . . Any discount or rebate that a third party is offering for EYLEA *will not and does not affect our ASP*.") (emphasis added).

117. By purporting not to offer price concessions on Eylea, Regeneron could market Eylea's stable ASP (and stable reimbursement) as a competitive advantage for retina practices when compared to Lucentis. Regeneron employed a team of "Reimbursement Business Managers" ("RBMs") for Eylea, who provided support for physicians' offices regarding the reimbursement cycle for Eylea. On March 8, 2013, a Regeneron RBM made the following slide and shared it with a colleague, with the subject line "asp over time updated FOR Q2 2013.xls" and a cover email stating: "This sort of thing could help RBMs understand this."

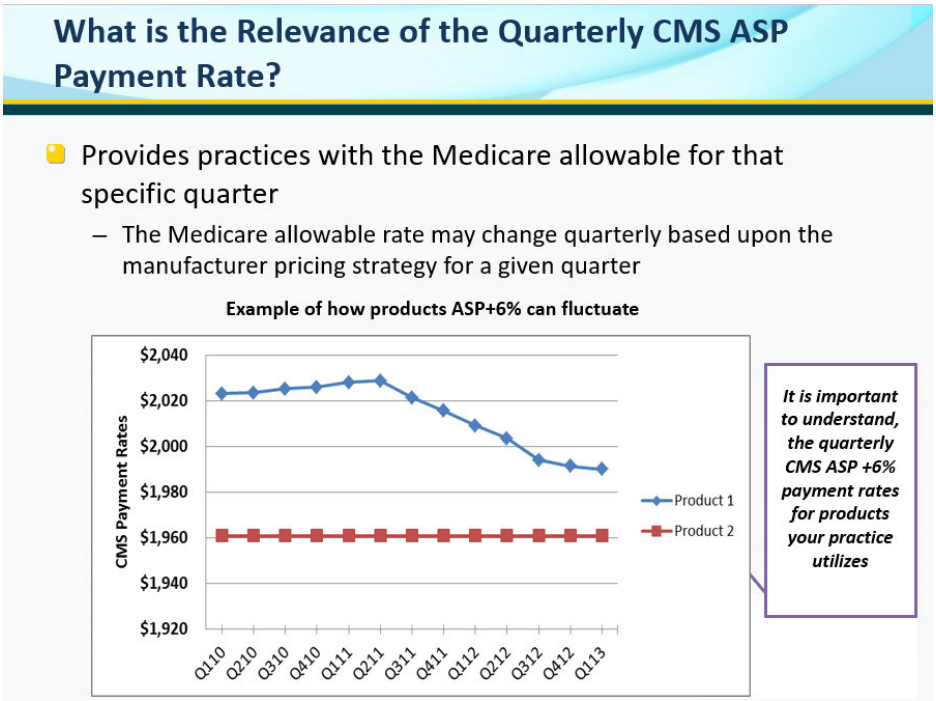


Ex. 47, at 6). As illustrated in the image, declining ASPs were referred to as "cliffs" because a manufacturer with a declining ASP had to offer ever-increasing discounts and rebates to maintain customers' "spreads"—leading to further declines in ASPs. The colleague responded:

> You go to the head of the class. This is exactly what has been added into the RBM deck that we will roll out next week minus the colorful graphic and the names of the drugs.

Ex. 48.

118. The approved marketing slide deck for Regeneron's RBMs, used in presentations to practices, included a slide with a similar chart that compared the ASPs of two drugs, referred to as "Product 1" (Lucentis) and "Product 2" (Eylea):



Ex. 49, at slide 10 (approved marketing presentation for Regeneron RBMs) (other attachments omitted). The slide also referenced "manufacturer pricing strategy" and stated: "It is important to understand the quarterly CMS ASP +6% payment rates for products your practice utilizes."

119. Regeneron falsely treated its payments of credit card processing fees as BFSFs to avoid negatively impacting Eylea's ASP.

120. Regeneron knew that its payment of credit card processing fees on behalf of customers was a price concession for many customers, and because Regeneron did not report them as price concessions, had the further benefit of not eroding Eylea's ASP. *See* Ex. 50, at slide 10 ("Majority of physicians receive credit card points on anti-VEGF purchases, *limiting the appeal of discounts*.") (emphasis added).

121. Regeneron knew that offering and reporting discounts would likely trigger a Genentech "response" that would "lead to a downward pricing spiral and "risk[] a price war[.]" Ex. 51, at slide 33 (Internal 2016 Regeneron presentation referencing the "Downward spiral of ASP impacts" as a "Cost" of providing rebates, with a "Risk [of] Price erosion" and that

Genentech would increase Lucentis offers "further risking a price war[.]"); *see also* Ex. 7, at slide 9.

122. Regeneron knew that Eylea's stable ASP gave it an advantage with customers, particularly customers with smaller volumes who were not eligible for large volume-based rebates that Genentech offered for Lucentis. *See* Ex. 52, at '927 (email to Mr. Davis, noting that Lucentis had the largest share among the "6-9 docs" and "10+ docs" groups and stating: "Interesting that smallest practices are highest users of Eylea. Possible that Lucentis rebates at that level are not substantial enough to sway choice?").

V. Regeneron Submitted False ASP Reports To CMS And Caused The Submission Of Materially False Claims To Medicare

A. By Knowingly Submitting False ASP Reports To CMS, Regeneron Submitted False Statements Material To False Claims

123. Regeneron submitted quarterly ASP reports for Eylea to CMS.

124. Regeneron did not deduct its credit card fee payments, or any portion thereof, as price concessions in its ASP reports for Eylea between 2012 and 2023.

125. As described above, Regeneron knew that reimbursing distributors for credit card processing fees incurred on Eylea purchases were price concessions to Eylea customers that should have been included in its ASP reports. *See* 42 C.F.R. § 414.804(a)(2)(i) ("In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions.")

126. Regeneron knowingly submitted ASP reports that were false because in those reports, Regeneron did not deduct its payments of credit card processing fees for Eylea as price concessions.

127. CMS relied on the accuracy of Regeneron's ASP submissions in setting payment rates under the Medicare Part B program.

128. Regeneron's false ASP reports materially inflated Medicare Part B reimbursement rates for Eylea.

B. Regeneron's False ASP Reports Caused The Submission Of False Claims To Medicare

129. Regeneron's failure to properly report credit card fees as price concessions caused the submission of hundreds of millions of dollars of false claims to Medicare.

130. At all relevant times, Regeneron knew that its customers submitted claims to Medicare for Eylea. Regeneron knew that the ASP it reported for Eylea impacted the reimbursement amounts Medicare paid for Eylea claims.

131. The table below includes representative examples of claims to Medicare for Eylea from the period during which Regeneron was falsely inflating Eylea's ASP.

Beneficiary Name	Beneficiary State	Date	Procedure Code	Medicare Amount Allowed	Medicare Amount Paid
R.N.	MA	03/28/2013	J0178	$1,961.00	$1,568.80
B.W.	MA	03/28/2014	J0178	$1,961.00	$1,537.42
I.C.	MA	03/27/2015	J0178	$1,961.00	$1,537.42
S.L.	MA	03/28/2016	J0178	$1,961.00	$1,537.42
L.B.	MA	03/28/2017	J0178	$1,960.76	$1,537.24
D.P.	MA	03/28/2018	J0178	$1,943.89	$1,524.01
M.R.	MA	03/28/2019	J0178	$1,927.07	$1,510.83
Z.G.	MA	03/27/2020	J0178	$1,890.06	$1,481.81
S.C.	MA	03/29/2021	J0178	$1,843.51	$1,474.81
R.M.	MA	03/28/2022	J0178	$1,831.49	$1,465.19
C.M.	MA	03/28/2023	J0178	$1,796.65	$1,408.57

C. Regeneron's Violations Were Material To Medicare's Payment Decisions

132. Because Medicare's reimbursement rates for Eylea were set based on ASP, Regeneron's falsely inflated ASP reports for Eylea were, under the plain terms of the statute, material to the amount Medicare paid for each Eylea claim. By inflating Eylea's ASP, Regeneron caused Medicare to reimburse each Eylea claim at a higher, inflated amount.

COUNT I
(False Claims Act: Causing False or Fraudulent Claims)
(31 U.S.C. § 3729(a)(1)(A))

133. The United States re-alleges and incorporates by reference the allegations of Paragraphs 1 through 132.

134. By virtue of the acts described above, Regeneron knowingly caused to be presented for payment or approval false or fraudulent Medicare claims, in violation of the False Claims Act, 31 U.S.C.§ 3729(a)(1)(A); that is, Regeneron knowingly caused Medicare Part B to pay inflated reimbursement amounts for each Eylea claim.

135. Payment of the false and fraudulent claims was a reasonable and foreseeable result of Regeneron's conduct.

136. By reason of the foregoing, the United States suffered actual damages because of Regeneron's wrongful conduct in an amount to be determined at trial and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false or fraudulent claim.

COUNT II
(False Claims Act: False Statements Material to False Claims)
(31 U.S.C. § 3729(a)(1)(B))

137. The United States re-alleges and incorporates by reference the allegations of Paragraphs 1 through 132.

138. By virtue of the acts described above, Regeneron knowingly made, used, or caused to be made or used false records or statements that were material to false or fraudulent Medicare claims; that is, Regeneron submitted fraudulent and inflated ASP reports to CMS.

139. The fraudulent ASP reports were material to, and Medicare actually relied on them, in determining Medicare reimbursement for claims for Eylea.

140. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of Regeneron's statements and actions.

141. By reason of the foregoing, the United States suffered actual damages because of Regeneron's wrongful conduct in an amount to be determined at trial and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false record or statement material to a false or fraudulent claim.

COUNT III
(Unjust Enrichment)

142. The United States re-alleges and incorporates by reference the allegations of Paragraphs 1 through 132.

143. The United States is entitled, under federal common law, to the recovery of monies by which Regeneron has been unjustly enriched due to its actions as described in this complaint.

144. By virtue of the conduct and acts described above, Regeneron was unjustly enriched at the expense of the United States in an amount to be determined, which, under the circumstances, in equity and good conscience, and as dictated by the needs of justice and fairness, should be returned to the United States or would be unconscionable for Regeneron to retain.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully prays for judgment in its favor as follows:

145. As to the First and Second Causes of Action (False Claims Act): for (i) statutory damages in an amount to be established at trial, trebled as required by law, and such penalties as are required by law; (ii) the costs of this action, plus interest, as provided by law, and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

146. As to the Third Cause of Action (Unjust Enrichment): for (i) a full accounting of all revenues (and interest thereon) and costs incurred by Regeneron on Eylea sales to Medicare patients based on inflated reimbursement rates due to Regeneron's conduct, and (ii) disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

147. All other and further relief as the Court may deem just and proper.

DEMAND FOR A JURY TRIAL

The United States hereby demands a jury trial on all claims alleged herein.

Dated: March 28, 2024

Respectfully submitted,

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